510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k041668

B. Purpose for Submission:
Change Indications for use to include cardiovascular use

C. Analyte:
C-reactive protein immunological test system

D. Type of Test:
Quantitative Immunoturbidimetirc

E. Applicant:
OLYMPUS AMERICA INC.

F. Proprietary and Established Names:
OLYMPUS CRP LATEX IMMUNOTURBIDIMETRIC REAGENT

G. Regulatory Information:

1. Regulation section:
   21CFR §866.5270 -C-reactive protein immunological test system.
2. Classification:
   Class 2
3. Product Code:
   NQD
4. Panel:
   Immunology (82)

H. Intended Use:

1. Indication(s) for use:
   System reagent for the quantitative determination of C-Reactive Protein in human serum on OLYMPUS Analyzers. Measurement of CRP is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases. Measurements may also be used as an aid in the identification of individuals at risk for future cardiovascular disease. High sensitivity CRP (hsCRP) measurements, when used in conjunction with traditional clinical laboratory evaluation of acute coronary syndromes, may be useful as an independent marker of prognosis for recurrent events, in patients with stable coronary disease or acute coronary syndromes.

2. Special condition for use statement(s):
   Prescription use only.

3. Special instrument requirements:
   Olympus AU400, AU600, AU640, and AU2700/5400

I. Device Description:

This in-vitro diagnostic device consists of ready to use diluent buffer and a latex solution consisting of latex particles coated with goat anti-CRP antiserum. Depending on the application used (different instrument settings) three measuring ranges are available:

1. Normal Application (5 – 170 mg/L): C-reactive protein levels in serum can rise dramatically after myocardial infarction, stress, trauma, infection, inflammation, surgery, or neoplastic proliferation. The increase occurs within 24 to 48 hours, and the level may be 2000 times normal. Because the increase is non-specific, however, it cannot be interpreted without a complete clinical history, and even then only by comparison with previous values.

2. Cardiac Application - (0.5 – 20.0 mg/L): Studies have also shown that the detection of much lower CRP levels can provide valuable information. The typical CRP concentration for healthy adults is (depending on the specific level of the individual patient) < 1 mg/L. Slightly higher values can indicate an increased risk for coronary heart disease in asymptomatic patients. CRP concentrations above 3 mg/L, at the time of hospital admission, predict a precarious outcome after a myocardial infarct . Increases in C-Reactive Protein values are not specific and should not be interpreted without a complete clinical history since CRP is an acute phase protein which can rise non-specifically due to other inflammatory conditions. For cardiac risk analysis, other cardiac disease-specific testing must be done, such as Total cholesterol, HDL cholesterol, and LDL cholesterol. When being used for risk assessment, levels of CRP > 10 mg/L should be evaluated for other non-cardiovascular origins. Testing for any risk assessment should not be performed while there is indication of infection, systemic inflammation, or trauma. This assay is not meant for management of acute coronary syndrome and is not a substitute for traditional cardiovascular risk factors. Screening the entire adult population for hsCRP is not recommended. The average of hsCRP levels determined two weeks apart should be used in performing risk assessment on metabolically stable patients. hsCP is considered to be a Class IIa marker for acute coronary syndrome in addition to Troponin I.

3. Neonatal Application (0.05 – 2.00 mg/L): Cord blood normally has very low CRP concentrations (median 0.12 mg/L7). In the diagnostic evaluation of neonates with suspected infection, measurements of serial CRP levels are useful. Two low CRP levels obtained 24 hours apart indicate that bacterial infection is highly unlikely. Thus, CRP Latex reagent is a valuable tool for the early diagnosis of infection in preterm infants and neonates. It assesses both the need for, and the effectiveness of,

antibiotic treatment. However, CRP values alone should not be used as a basis for early discontinuance of antibiotic therapy.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   OLYMPUS CRP LATEX IMMUNOTURBIDIMETRIC REAGENT
   DADE BEHRING, N HIGH SENSITIVITY CRP
2. Predicate K number(s):
   k002918
   k991385/k033908
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Reagent and all performance	Unchanged	Unchanged
Differences		
Item	**Device**	**Predicate**
Indications for use	System reagent for the quantitative determination of C-Reactive Protein in human serum on OLYMPUS Analyzers. Measurement of CRP is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases. Measurements may also be used as an aid in the identification of individuals at risk for future cardiovascular disease. High sensitivity CRP (hsCRP) measurements, when used in conjunction with traditional clinical laboratory evaluation of acute coronary syndromes, may be useful as an independent marker of prognosis for recurrent events, in patients with stable coronary disease or acute coronary syndromes.	The Olympus CRP Latex Immunoturbidimetric Reagent is intended for use in the quantitative determination of C-Reactive Protein levels in Human Serum.

K. Standard/Guidance Document Referenced (if applicable):

AHA/CDC Scientific Statement (Circulation, 2003; 107:499-511)

L. Test Principle:

Immune complexes formed in solution scatter light in proportion to their size, shape, and concentration. Turbidimeters measure the reduction of incidence light due to reflection, absorption, or scatter. In this Olympus procedure, the measurement of the rate of decrease in light intensity transmitted (increase in absorbency) through particles suspended in solution is the result of complexes formed during the immunological reaction between the CRP of the patient serum and goat anti-CRP antibodies coated on latex particles.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
    - *a. Precision/Reproducibility:*
      Not Applicable subject of k002918
    - *b. Linearity/assay reportable range:*
      Not Applicable subject of k002918
    - *c. Traceability (controls, calibrators, or method):*
      Not Applicable subject of k002918
    - *d. Detection limit:*
      Not Applicable subject of k002918
    - *e. Analytical specificity:*
      Not Applicable subject of k002918
    - *f. Assay cut-off:*
      Not Applicable subject of k002918
2. Comparison studies:
    - *a. Method comparison with predicate device:*
      Not Applicable subject of k002918
    - *b. Matrix comparison:*
      Not Applicable subject of k002918
3. Clinical studies:
    - *a. Clinical sensitivity:*
      Not Applicable
    - *b. Clinical specificity:*
      Not Applicable
    - *c. Other clinical supportive data (when a and b are not applicable):*
      Subject device showed comparable analytical performance in its original submission (k002918) to the DADE BEHRING, N HIGH SENSITIVITY CRP (k991385/k033908). The DADE BEHRING, N HIGH SENSITIVITY CRP assay was the device used in the clinical studies supporting an indication for cardiovascular use.
4. Clinical cut-off:
   The cutoff was established previously in the literature not with this device.
5. Expected values/Reference range:
   The expected range was established in the literature not with this device.

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.